

## WHAT IS CLAIMED IS:

1. A discrete solid orally deliverable pharmaceutical dosage form comprising a plurality of zones, wherein (a) at least one zone comprises an NSAID, the NSAID being present in a therapeutically effective total amount in the dosage form; (b) at least one zone, other than a zone comprising the NSAID, comprises HPMC having dispersed therein a prostaglandin type compound in a form of a substantially water-free solid dispersion, the prostaglandin type compound being present in the dosage form in a total amount effective to mitigate a gastric ulcerogenic effect of the NSAID; (c) said plurality of zones are spatially arranged such that, if there is only one NSAID-containing zone and one prostaglandin-containing zone, said NSAID-containing and prostaglandin-containing zones are arranged other than as a core and mantle respectively having an enteric coating layer therebetween; and (d) said HPMC comprises a fraction having particle size smaller than about 53  $\mu\text{m}$ , said fraction exhibiting, upon dissolution in CO<sub>2</sub>-free purified water to form a 1% weight/volume solution, a pH not lower than about 4.
2. The dosage form of Claim 1 having one NSAID-containing zone and one prostaglandin-containing zone.
3. The dosage form of Claim 2 that is a bilayer tablet wherein said NSAID-containing zone and said prostaglandin-containing zone are disposed as layers.
4. The dosage form of Claim 2 that is a dual-compartment capsule wherein said NSAID-containing zone and said prostaglandin-containing zone are disposed as compartments.
5. The dosage form of Claim 2 wherein said NSAID-containing zone and said prostaglandin-containing zone are disposed as pre-compressed or pre-molded tablets embedded within a single larger dosage form.
6. The dosage form of Claim 2 that is a tablet having a core comprising said prostaglandin type compound surrounded by a mantle comprising said NSAID.
7. The dosage form of Claim 1 having more than two of said zones.
8. The dosage form of Claim 7 that is a multilayer tablet wherein said at least one NSAID-containing zone and said at least one prostaglandin-containing zone are

disposed as layers.

9. The dosage form of Claim 8 comprising two outer prostaglandin-containing layers having sandwiched between them a middle NSAID-containing layer.
10. The dosage form of Claim 7 wherein said zones are disposed as a plurality of separately NSAID-containing and prostaglandin-containing particles compressed or molded into a single tablet.
11. The dosage form of Claim 7 that is a multi-compartment capsule wherein said at least one NSAID-containing zone and said at least one prostaglandin-containing zone are disposed as compartments.
12. The dosage form of Claim 7 that is a capsule containing a plurality of separately NSAID-containing and prostaglandin-containing beads.
13. The dosage form of Claim 7 that is a capsule containing a plurality of beads, at least a fraction of said beads individually comprising a core comprising said NSAID surrounded by a mantle comprising said prostaglandin type compound.
14. The dosage form of Claim 1, further comprising a barrier layer having the effect of substantially preventing contact of the NSAID with the prostaglandin type compound.
15. The dosage form of Claim 1 wherein said fraction of the HPMC exhibits, upon dissolution in CO<sub>2</sub>-free purified water to form a 1% weight/volume solution, a pH not lower than about 4.5.
16. The dosage form of Claim 1 wherein said fraction of the HPMC exhibits, upon dissolution in CO<sub>2</sub>-free purified water to form a 1% weight/volume solution, a pH not lower than about 5.
17. The dosage form of Claim 1 wherein said fraction of the HPMC exhibits, upon dissolution in CO<sub>2</sub>-free purified water to form a 1% weight/volume solution, a pH not lower than about 6.
18. The dosage form of Claim 1 wherein said prostaglandin type compound is selected from prostaglandins E<sub>1</sub> and E<sub>2</sub> and derivatives thereof.
19. The dosage form of Claim 1 wherein said prostaglandin type compound is

misoprostol.

20. The dosage form of Claim 19 wherein said misoprostol is dispersed in said HPMC in a weight ratio of about 1:1000 to about 1:10.
21. The dosage form of Claim 19 wherein said misoprostol is dispersed in said HPMC in a weight ratio of about 1:500 to about 1:20.
22. The dosage form of Claim 19 wherein said misoprostol is dispersed in said HPMC in a weight ratio of about 1:200 to about 1:50.
23. The dosage form of Claim 19 wherein said misoprostol is present in the dosage form in a total amount of about 50 to about 400  $\mu\text{g}$ .
24. The dosage form of Claim 19 wherein said misoprostol is present in the dosage form in a total amount of about 100 to about 300  $\mu\text{g}$ .
25. The dosage form of Claim 1 wherein said NSAID is selected from diclofenac and its pharmaceutically acceptable salts, and piroxicam.
26. The dosage form of Claim 1 wherein said NSAID is diclofenac sodium.
27. The dosage form of Claim 26 wherein said diclofenac sodium is present in the dosage form in a total amount of about 20 to about 200 mg.
28. The dosage form of Claim 26 wherein said diclofenac sodium is present in the dosage form in a total amount of about 40 to about 100 mg.
29. The dosage form of Claim 1 wherein said NSAID is diclofenac sodium in a total amount of about 50 mg and said prostaglandin type compound is misoprostol in a total amount of about 200  $\mu\text{g}$ .
30. The dosage form of Claim 1 wherein said NSAID is diclofenac sodium in a total amount of about 75 mg and said prostaglandin type compound is misoprostol in a total amount of about 200  $\mu\text{g}$ .
31. An assay method for selecting lots of HPMC suitable for use in preparing a solid dispersion of a prostaglandin type compound, the method comprising (a) fractionating a sample of a test lot of HPMC by particle size to provide a sub-53  $\mu\text{m}$  fraction; (b) dissolving said fraction in  $\text{CO}_2$ -free purified water to provide a 1% weight/volume solution; (c) measuring pH of said solution; and (d) selecting the test

lot for said use if the pH is 4.0 or higher.

32. A process for preparing a solid dispersion of a prostaglandin type compound in HPMC comprising a step of selecting a lot of HPMC by the assay method of Claim 31.
33. A process for preparing a dosage form of Claim 1 comprising a step of selecting a lot of HPMC by an assay method that comprises (a) fractionating a sample of said lot of HPMC by particle size to provide a sub-53  $\mu\text{m}$  fraction; (b) dissolving said fraction in  $\text{CO}_2$ -free purified water to provide a 1% weight/volume solution; (c) measuring pH of said solution; and (d) selecting the test lot for preparing said dosage form if the pH is 4.0 or higher.
34. A process for preparing a dosage form of Claim 1 comprising a step of treating said HPMC such that, following such treatment, a fraction of said HPMC having particle size smaller than about 53  $\mu\text{m}$  exhibits, upon dissolution in  $\text{CO}_2$ -free purified water to form a 1% weight/volume solution, a pH not lower than about 4.
35. The process of Claim 34 wherein said treatment comprises milling the HPMC.
36. The process of Claim 34 wherein said treatment comprises adding a pH modifying agent to the HPMC.
37. The process of Claim 36 wherein the pH modifying agent is a base.
38. The process of Claim 34 wherein said treatment comprises vacuum drying the HPMC.